TEXAS DEPARTMENT OF HEALTH
GUIDELINES FOR THE TEXAS MEDICATION PROGRAM

BACKGROUND - The Texas Department of Health (TDH) has received funding to help offset the cost of medications approved by the Food and Drug Administration (FDA) for the treatment of HIV infection. The program is available to eligible indigent persons with HIV infection, and will provide the following:

PRIORITY 1 MEDICATIONS AND CRITERIA

Antiretroviral Options - A maximum of four (4) of the following medications is allowed:

(1) Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

Zidovudine (AZT, Retrovir)
Didanosine (DDI, Videx)
Zalcitabine (DDC, Hivid)
Stavudine (D4T, Zerit)
Lamivudine (3TC, Epivir)
Combivir (AZT 300mg/3TC 150mg) **(Counts as two (2) medications)**
Abacavir (Ziagen)

(2) Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) - For Non-Medicaid clients only.
Medicaid eligible clients must receive these medications through their Medicaid.

Nevirapine (Viramune)
Delavirdine (Rescriptor)
Efavirenz (Sustiva)

(3) Protease Inhibitors (PIs) * - For Non-Medicaid clients only.
Medicaid eligible clients must receive these medications through their Medicaid.

Fortovase softgel (Saquinavir)
Invirase (Saquinavir) **
Ritonavir (Norvir) **
Indinavir (Crixivan)
Nelfinavir mesylate (Viracept)

Antiretroviral Qualifications - A person must be:

Diagnosed with HIV infection and have a current CD4+ T Lymphocyte count and Plasma RNA Viral Load count reported to the Texas Medication Program prior to receiving medication.

Newborn infants and pregnant women are a program priority.

* Any combination requests that include both Invirase (Saquinavir) and Ritonavir (Norvir) will be approved for the reduced dosage regimen...(Invirase 200 mg, #270 / 2 months and Ritonavir 100 mg, #252 / 1 month).

** Any combination requests that include both Fortovase Softgel Tablets (Saquinavir) and Ritonavir (Norvir) will be approved for the following regimen...(Fortovase 200 mg, #180 / 42 day supply and Ritonavir 100 mg, #336 / 45 day supply).

PRIORITY 1 MEDICATIONS AND CRITERIA - (continued)

(4) Sulfamethoxazole-Trimethoprim (SMZ-TMP), Dapsone or Trimethoprim - Diagnosed HIV infection and a CD4 cell count ≤ 200 or constitutional symptoms such as thrush or unexplained fever greater than 100°F for greater than two weeks; children under the age of 13 with ACTG clinical indicators.

(5) Acyclovir (Zovirax) - Diagnosed HIV infection and acute or chronic herpetic infections.

(6) Immune Globulin Intravenous (Human) (IVGG) - Diagnosed HIV infection and younger than 18 years of age.

PRIORITY 2 MEDICATIONS AND CRITERIA

(7) Pentamidine (aerosolized) - Diagnosed HIV infection and a CD4 cell count ≤ 200 or constitutional symptoms such as thrush or unexplained fever greater than 100°F for greater than two weeks; children under the age of 13 with ACTG clinical indicators.

(8) Pentamidine (intravenous) - Diagnosed HIV infection and ≤ 13 years of age.

(9) Fluconazole (Diflucan) - Diagnosed HIV infection and cryptococcal meningitis or esophageal candidiasis. Procedural or laboratory documentation of cryptococcal meningitis and/or esophageal candidiasis is required. Examples: esophoscopic or radiographic report of esophageal involvement. *Fungal cultures are not acceptable.*

(10) Itraconazole Suspension (Sporanox Susp.) - Diagnosed HIV infection and esophageal candidiasis. Procedural or laboratory documentation of esophageal candidiasis is required. Examples: esophoscopic or radiographic report of esophageal involvement. *Fungal cultures are not acceptable.*

(11) Itraconazole capsules (Sporanox caps) - Diagnosed HIV infection and diagnosed histoplasmosis or blastomycosis.

(12) Clarithromycin (Biaxin) - Diagnosed HIV infection and current or previous diagnosis of Mycobacterium Avium Complex (MAC).

(13) Azithromycin (Zithromax) - Diagnosed HIV infection and current or previous MAC diagnosis and failed therapy on, or intolerance to, Clarithromycin.

(14) Ganciclovir (Cytovene) - HIV infection and CMV disease which has resulted in retinitis or infections of other major organs or organ systems. Procedural or laboratory documentation of organ or retinal CMV infection is required. Examples: report of fundoscopic examination or pathology report of CMV infection from a biopsy of an organ or other tissue. *CMV cultures and/or testing are not acceptable.*

PRIORITY 3 MEDICATIONS AND CRITERIA - CURRENTLY NOT AVAILABLE

(15) Megestrol Acetate (Megace) - AIDS diagnosis and cachexia or anorexia with profound, involuntary, acute weight loss greater than or equal to 10% of baseline body weight or chronic weight loss greater than or equal to 20% of baseline body weight.

(16) Atovaquone (Mepron) - Diagnosed HIV infection and acute, mild to moderate Pneumocystis carinii Pneumonia (PCP) and intolerance to Sulfamethoxazole-Trimethoprim (SMZ-TMP).

(17) Interferon-Alpha - Diagnosed HIV infection and diagnosed, disseminated Kaposi's Sarcoma with a CD4 count > 200.

PRIORITY 3 MEDICATIONS AND CRITERIA - CURRENTLY NOT AVAILABLE - (continued)

(18) Amphotericin-B - Diagnosed HIV infection and progressive, potentially fatal disseminated fungal infections.

(19) Rifabutin (Mycobutin) - Diagnosed HIV infection and a CD4 cell count ≤ 100.

(20) Ethambutol (Myambutol) - Diagnosed HIV infection and current or previous diagnosis of MAC.

MEDICATION PRIORITIZATION - Providing medications according to their priority will serve as the budgetary control to purchase ALL medications on the formulary. See priorities below.

PRIORITY 1

Nucleoside Analogue Reverse Trascriptase Inhibitors
Didanosine (DDI) (Videx)
Stavudine (D4T) (Zerit)
Zalcitabine (DDC) (Hivid)
Zidovudine (AZT) (Retrovir)
Lamivudine (3TC) (Epivir)
Combivir (AZT 300/3TC 150)
Abacavir (Ziagen)

Protease Inhibitors
Fortovase (Saquinavir)
Invirase (Saquinavir)
Ritonavir (Norvir)
Indinavir (Crixivan)
Nelfinavir (Viracept)

PCP Medications
SMZ/TMP (Bactrim)
Dapsone
Trimethoprim

Non-Nucleoside Reverse Transcriptase Inhibitor
Nevirapine (Viramune)
Delavirdine (Rescriptor)
Efavirenz (Sustiva)

Antiviral
Acyclovir (Zovirax)

Bacterial Infections
IVIG (pediatric only)

PRIORITY 2

Mycobacterial Infections
Azithromycin (Zithromax)
Clarithromycin (Biaxin)

PCP Medications
Pentamidine (Nebupent)

Antiviral
Oral Ganciclovir
IV Ganciclovir (Cytovene)

Antifungal
Itraconazole (Sporanox)
Fluconazole (Diflucan)

PRIORITY 3 - CURRENTLY NOT AVAILABLE

PCP Medications
Atovaquone (Mepron)

Neoplasms
Interferon-Alpha (Roferon-A)

Antifungal
Amphotericin-B

Other
Megesterol Acetate (Megace)

Mycobacterial Infections
Ethambutol (Myambutol)
Rifabutin (Mycobutin)

ELIGIBLE PERSONS - Any Texas resident who:

(1) has a diagnosis of HIV disease and meets the drug-specific eligibility criteria of one or more of the drugs listed above and;

(2) is under the care of a Texas-licensed physician who prescribes the medication(s) and;

(3) meets the financial eligibility criteria of the program.

CRITERIA FOR FINANCIAL ELIGIBILITY - A person is financially eligible if he or she:

(1) is not presently covered for the medication(s) under the Texas Medicaid Program, or has utilized their Medicaid pharmacy benefits for the month and;

(2) is not covered for the medication(s) by any other third-party payor and;

(3) has an income, when combined with the income of his/her spouse, that does not exceed 200 percent of the current Federal Poverty Income Guidelines (as shown below). TDH will determine if the person satisfies this criterion from information provided by the person on the Program application.

If the demand for the priority 1 medications increases beyond the budget capacity to continue to furnish all the medications on the formulary, the program will begin to eliminate the medications in priority 3 and then priority 2, as necessary. The program will not abruptly cease purchasing priority 2 and 3 medications. The process will be gradual to allow individuals currently taking priority 2 and 3 medications an opportunity to look for other programs to provide these medications. Providing medications according to their priority will serve as the budgetary control to purchase all medications on the formulary.

INCOME GUIDELINES

If the size of the family unit is:	The family gross annual income may not exceed:
1	$16,480
2	$22,120
3	$27,760
4	$33,400
5	$39,040
>5	$ 5,640 each additional person

OBTAINING THE APPLICATION MATERIALS - An application packet, containing instructions and all necessary forms, may be requested by telephoning toll-free 1-800-255-1090 or writing to the:

Texas Department of Health
Texas Medication Program
1100 West 49th Street
Austin, Texas 78756

ATTN: MSJA

DEFINITION OF FAMILY AND HOUSEHOLD FOR DETERMINING FAMILY SIZE/INCOME - Family members whose incomes are considered are the applicant and his or her spouse, if applicable. For minor children, the child's parents' income is considered. (These persons must be living in the same household.) For determining household size, the applicant, spouse, and their dependent children shall be included. A dependent child is a child under the age of 18 who is the biological, adoptive, or stepchild of the applicant. A child applicant is a person under the age of 18, living with his or her parent(s).

FOSTER CHILDREN - In cases where a welfare agency is legally responsible for the child and the foster home is, in fact, an extension of the welfare agency, the foster child is considered a one member family. Therefore, if the foster child's income is not above the income guidelines, the foster child meets the income criteria.

DOCUMENTATION OF FINANCIAL ELIGIBILITY - The applicant must document his or her income on the application form, and provide verification of income with check stubs, W-2 forms, copies of benefit entitlement letters. If zero income is reported, the income verification form must be completed along with a letter of explanation signed by the applicant explaining when and where he/she was last employed and how he/she is able to live on zero income/cash assistance.

DOCUMENTATION OF MEDICAL ELIGIBILITY - All applications for new clients must be mailed in to the program. Medical Certification Forms must be submitted for all medication changes. The medical certification forms should only be faxed for clients in immediate need of changes to be made to their approved formulary so as not to disrupt their progress on combination antiretroviral therapy.

DETERMINING INITIAL FINANCIAL ELIGIBILITY - Using the current Public Health Service discount prices, TDH will calculate the annual cost of Program formulary medications that the applicant's physician has qualified them for, and subtract that amount from his/her gross annual income. If the applicant's adjusted gross income at the time of application is below the guidelines, he/she is financially eligible. If income is above the guidelines, he/she is financially ineligible. The applicant should be encouraged to request reconsideration if his/her income status changes such that it is within the Program parameters.

CONFIDENTIALITY - TDH regards the information in the application as part of the applicant's medical record and confidential by law. No information that could identify the individual applicant will be released except as authorized by law. Within TDH, physical security and administrative controls exist to safeguard the confidentiality of the applications and other means of identifying the individual. Applicants should realize that, in addition to TDH, their physician and pharmacist will be aware of the diagnosis.

PROVISION OF MEDICATION(S) - The Program will provide the following medication(s) each month:

PRIORITY 1 MEDICATION STRENGTHS AND MAXIMUM QUANTITIES

(1) A maximum of 400 capsules of 100mg zidovudine (AZT, Retrovir) - #100/btl, or
A maximum of 60 tablets of 300mg zidovudine (AZT, Retrovir) - #60/btl;

O Zidovudine suspension must be provided in 8oz (240ml) bottles.
O IV zidovudine must be provided in 10mg/ml - 2 ml vials.

(2) A maximum of 120 tablets of didanosine (DDI, Videx) - #60/btl, or
A maximum of 60 powder packets of didanosine (DDI, Videx) - #30/pkg;

O strengths available are 25mg, 50mg, 100mg or 150mg tablets;
100mg, 167mg or 250mg powder packets; or 2gm or 4gm pediatric powder.

(3) A maximum of 100 tablets of zalcitabine (DDC, Hivid) - #100/btl;

O strengths available are 0.375mg, or 0.750mg.

(4) A maximum of 60 capsules of stavudine (D4T, Zerit) - #60/btl;

O strengths available are 15mg, 20mg, 30mg or 40mg.

(5) A maximum of 60 capsules of 150mg lamivudine (3TC, Epivir) - #60/btl;

(6) A maximum of 60 tablets of Combivir (AZT 300mg/3TC 150mg) - #60/btl;

(7) A maximum of 60 tablets of 300mg abacavir sulfate (Ziagen) - #60/btl;
O Abacavir suspension must be provided in 8oz (240ml) bottles.

(8) A maximum of 540 capsules of 200mg fortovase softgel (Saquinavir) - #180/btl, or
A maximum of 180 capsules of 200mg fortovase if used with Norvir - #180/btl;

O The fortovase #180/Norvir #336 combination will last 45/42 days respectively - must allow at least 30 days between orders.

(9) A maximum of 270 tablets of 200mg invirase (Saquinavir) - #270/btl, or

O A maximum of 270 tablets of 200mg invirase (Saquinavir) every 2 months when used in combination with ritonavir (Norvir).

(10) A maximum of 336 tablets of 100mg ritonavir (Norvir) - #168/btl, or
A maximum of 2 bottles of 80 mg/ml-240 ml (8 oz) ritonavir (Norvir) suspension;

(11) A maximum of 270 tablets of 200mg indinavir (Crixivan) - #270/btl, or
A maximum of 360 tablets of 200mg indinavir (Crixivan) - #360/btl, or
A maximum of 180 tablets of 400mg indinavir (Crixivan) - #180/btl;

(12) A maximum of 270 tablets of 250mg nelfinavir mesylate (Viracept) - #270/btl, or

O Nelfinavir oral powder available in 50mg/gm, 144gm bottle for pediatric use.

(13) A maximum of 100 tablets of 200mg nevirapine (Viramune) - #100/btl;

(14) A maximum of 360 capsules of 100mg delavirdine (Rescriptor) - #360/btl;

(15) A maximum of 90 capsules of 200mg efavirenz (Sustiva) - #90/btl, or
A maximum of 30 capsules of 100mg efavirenz (Sustiva) - #30/btl, or
A maximum of 30 capsules of 50mg efavirenz (Sustiva) - #30/btl;

(16) A maximum of 200 tablets of 800/160mg SMZ-TMP (Bactrim) - #100/btl, or

O SMZ-TMP suspension must be provided in 473ml (1 pint) bottle.

(17) A maximum of 100 tablets of 100mg dapsone - #100/btl;

(18) A maximum of 100 tablets of 200mg trimethoprim - #100/btl;

O TDH provides either SMZ-TMP, dapsone or pentamidine each month.

(19) A maximum of 200 capsules of acyclovir (Zovirax) - #100/btl;

O strengths available are 200mg or 800mg.

PRIORITY 2 MEDICATION STRENGTHS AND MAXIMUM QUANTITIES

(20) One 300 mg. vial of aerosolized pentamidine (Nebupent) - 1 vial;

O TDH provides either pentamidine, SMZ-TMP, or dapsone each month.

(21) A maximum of 60 tablets of fluconazole (Diflucan) - #30/btl;

O strengths available are 50mg, 100mg or 200mg.

(22) A maximum of 90 capsules of 100mg itraconazole (Sporanox) - #30/btl, or
A maximum of 2 bottles of 10mg/ml itraconazole suspension - 150ml/btl;

(23) A maximum of 60 tablets of 500mg clarithromycin (Biaxin) - #60/btl, or

(24) A maximum of 60 tablets of 250mg azithromycin (Zithromax) - #30/btl, or
A maximum of 30 tablets of 600mg azithromycin (Zithromax) - #30/btl;

(25) A maximum of 360 capsules of 250mg ganciclovir (Cytovene) - #180/btl, or
A maximum of 180 capsules of 500mg ganciclovir (Cytovene) - #180/btl, or
A maximum of 50 vials of 500mg IV ganciclovir (IV Cytovene);

PRIORITY 3 MEDICATION STRENGTHS AND MAXIMUM QUANTITIES - CURRENTLY NOT AVAILABLE

(26) A maximum of 3 bottles of 40mg/ml megestrol acetate (Megace) - 240ml btl;

(27) A maximum of 2 bottles of 750mg/5ml atovaquone suspension (Mepron) per 21-day treatment therapy following **each** diagnosis of PCP - 210ml btl;

(28) A maximum of 50 vials of 18mu interferon-alpha;

(29) A maximum of 50 vials of 50mg amphotericin-B;

(30) A maximum of 100 capsules of 150mg rifabutin (Mycobutin) per 7-week period - #100/btl;

(31) A maximum of 100 tablets of 400mg ethambutol (Myambutol) - #100/btl.

O ALL MEDICATIONS MUST BE DISPENSED IN FULL BOTTLE AMOUNTS.

PAYMENT OF A FEE BY THE PATIENT - Persons who have been approved by TDH for Program financial assistance and are not Medicaid eligible may be required to pay a $5.00 prescription fee (co-payment) to the participating pharmacy for each month's supply at the time the drug is dispensed.

MEDICAID ELIGIBLE APPLICANTS - Applicants who are eligible for Medicaid assistance benefits must first utilize their Medicaid pharmacy benefits in order to be eligible to receive medications from the Program. Medicaid eligible applicants will be assigned to the nearest available pharmacy outlet to receive medication. The pharmacy will not charge the $5.00 co-payment to the patient.

PARTICIPATING PHARMACY - TDH has designated specific pharmacies throughout the state to dispense medications for approved Program clients. In order to obtain optimal physical security of the drugs and administrative control of the program, persons approved for the Program must obtain their medications from the pharmacy to which they are assigned. Should the pharmacy assignment prove a hardship to the patient, they must explain to TDH in writing why a hardship exists. The applicant must include in the explanation the name, address, and person to contact at the pharmacy where they would like to receive their medication(s). TDH will supply that pharmacy with a Program pharmacy agreement to complete and return to the Department.

PROCEDURE FOR RECEIVING MEDICATION - An approved Program patient will receive the prescription(s) from his or her physician, or have the physician phone prescription(s) in to the pharmacy each month for medication covered by the Program and present it to the assigned pharmacy. The pharmacy will order the medication from the Program using the assigned patient code and dispense to the patient upon receipt of the medication from the pharmaceutical supplier(s).